IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: : U.S. Patent No. 5,451,233 (U.S.S.N. 08/208,972)

Issued: : September 19, 1995 Regulatory Approval Product: XIENCE™ V EECSS

Inventors : Paul G. Yock

For : Angioplasty Apparatus Facilitating Rapid Exchanges

DISCLOSURE SUBMISSION PURSUANT TO 37 CFR § 1.765

SUBMITTED VIA EXPRESS MAIL
Mail Stop: Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the interview ("the Interview") held between the undersigned and Mary Till at the U.S. Patent and Trademark Office ("USPTO") on September 3, 2008, Applicant formally submits herewith information and materials that may be relevant to a determination of entitlement to the extension sought pursuant to 35 U.S.C. § 156 for U.S. Patent No. 5,451,233 ("the '233 Patent"). Although not necessarily material or adverse to any such determination, the following information and materials were discussed during the Interview and offered for further consideration pursuant to 37 C.F.R. § 1.765. A copy of the corresponding Interview Summary is enclosed as Appendix A.

Background to Rapid Exchange Catheters and Stent Systems

Medical devices have been used to treat coronary artery disease at least since the mid-1980s. Balloon catheters are a first type of interventional product approved by the Food and Drug Administration ("FDA") to treat coronary disease. Balloon dilatation catheters are used in

a procedure known as percutaneous transluminal coronary angioplasty ("PTCA"), wherein the catheter is introduced within the femoral artery, through the aorta, and into the coronary artery to be treated. Once properly situated, a balloon disposed near the tip of the balloon dilatation catheter is inflated to compress fatty deposits that have accumulated inside the artery to open the lesion site. From the mid 1980s until the early-to-mid 1990s, balloon dilatation catheters were a predominate medical device used for treatment of coronary disease. Applicant, through a predecessor company, obtained FDA approval for a number of balloon dilatation catheters, such as the ACS RX® Alpha Coronary Dilatation Catheter (*see*, PMA P810046, Supplement S067).

By the mid 1990s, a second type of product, generally known as a bare-metal coronary stent system, was approved by the FDA and commercially introduced in the United States. Bare-metal coronary stent systems include a balloon dilatation catheter to compress fatty deposits and open the lesion site, as well as to implant a stent (i.e., small, expandable metal scaffold) to aid in maintaining the open pathway through the artery. The Multi-Link Vision® RX Coronary Stent System, which was demonstrated during the Interview with Ms. Till, is an example of a coronary bare-metal stent system approved by the FDA. (*See*, PMA P020047)

In the early-to-mid 2000s, a third type of product, generally known as drug-eluting coronary stent systems (a.k.a.,"drug-eluting stents"), was approved by the FDA and commercially introduced to the United States. Drug-eluting coronary stent systems include a balloon dilatation catheter and a stent including one or more polymer coatings, one or more of which contain a drug that is released over time to inhibit or prevent blockages from re-forming at the lesion site. The XIENCE™ V EECSS is the first drug-eluting coronary stent system approved by the FDA for Applicant. (*See*, PMA P070015)

The XIENCE™ V EECSS differs from the Multi-Link Vision® RX Coronary Stent System. For example, and unlike the Multi-Link Vision® RX Coronary Stent System or any other bare-metal coronary stent system, the XIENCE™ V EECSS has a polymer coating including a coating of poly n-butyl methacrylate (PMBA) applied to the stent surface and an outer polymer coating of vinylidene fluoride and hexafluoropropylene monomers (PVDF-HFP). The PVDF-HFP coating of the XIENCE™ V EECSS contains the drug everolimus, which is eluted over time into the artery wall. (*see, e.g.*, Exhibit E of the PTE Application filed July 25, 2008, pages 4-6). Hence, the XIENCE™ V EECSS, which was reviewed and approved as a medical device under Section 515 of the FDA Act, as a whole includes at least four major

components (and many subcomponents): (i) balloon dilatation catheter, (ii) coronary stent, (iii) polymer coating, and (iv) drug. The Multi-Link Vision® RX Coronary Stent System does not include this same combination of components, and indeed the Multi-Link Vision® RX Coronary Stent System does not even include two of these components. Hence, the XIENCE™ V EECSS is the first drug-eluting stent system product approved for Applicant by the FDA.[1]

The '233 Patent generally relates to a type of balloon dilatation catheter referred to as "rapid exchange" or "RX." Rapid exchange allows a single operator to quickly and easily load or exchange a balloon dilatation catheter during the interventional procedure. Rapid exchange balloon dilatation catheters have been approved since at least 1990. Applicant has developed and obtained approval from the FDA for a rapid exchange version of each of the three types of products referenced above. Attached as Appendix B is a non-exhaustive listing of approvals by the FDA for rapid exchange versions of each of these three product types.

Summary of Prior and Current Litigation Involving the '233 Patent

The '233 Patent has been the subject of various actions as summarized in Appendix C attached hereto.

In one such action, *Advanced Cardiovascular Systems, Inc. v. Medtronic, Inc.* (C.A. No. 95-03577), claim 3 of the '233 Patent was found, on summary judgment, by the Northern District of California to be valid, enforceable, and infringed. The Federal Circuit affirmed the Northern District of California's judgment on all appealed issues, including the enforceability of claim 3 of the '233 Patent (Federal Circuit Case No. 00-1417). The defendant, Medtronic, Inc., was found to willfully infringe claim 3 of the '233 patent and was permanently enjoined from making, using, offering for sale, or selling the infringing Falcon, a balloon dilatation catheter, and any colorable variation of the Falcon catheter which infringes the '233 Patent "until October 29, 2008, or other legal expiration of the '233 patent."

[1] Note, the extension sought in this application can be distinguished from situation involving U.S. Patent No. 5,299,569 ('569 patent). Particularly, the extension sought for the '569 patent was based upon a Vagus Nerve Stimulator ("VNS"), which was acknowledged to be for the "same device" as previously approved by the FDA. By contrast, the extension sought in this application is based upon the first approval by the FDA of a new medical device.

On August 15, 2008, Medtronic moved to modify this injunction such that the injunction would be dissolved as of October 29, 2008. A copy of the Motion filed by Medtronic is attached as Appendix D.

On September 12, 2008, Abbott filed an Opposition to Medtronic's Motion. A redacted version of the Opposition is attached as Appendix E. The redacted portion of the Opposition pertains to, and quotes from, an award entered to Applicant's predecessor in a previous arbitration proceeding, which Medtronic successfully moved to have placed under seal before the United States District Court for the Northern District of California. It is noted that an unredacted version of the Opposition has been filed with the Court, under seal. Should the USPTO desire or need to review the redacted portion of Abbott's Opposition, Applicant will approach Medtronic to seek permission to submit the unredacted version of the Opposition.

In the Opposition to Medtronic's Motion, Abbott sets forth at least some of the bases for and reasons why the '233 Patent is eligible for an extension under 35 U.S.C. §156. Abbott notes that such an extension of the '233 Patent is consistent with the plain language of Section 156, its legislative history, Federal Circuit precedent (including *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 381 F.3d 1371 (Fed. Cir. 2004)), and the USPTO's interpretation of Section 156 -- as set forth in Exhibit 16 of Medtronic's Motion (a February 2008 letter from the Director of the Office of Governmental Affairs for the USPTO, Jefferson D. Taylor, to The Hon. Howard L. Berman), as well as by the interpretation afforded to previous PTE applications filed by Medtronic that were granted or found eligible to be granted.

On September 19, 2008, Medtronic filed a Reply in support of its Motion to modify. A redacted version of the Reply filed by Medtronic is attached as Appendix F, wherein the redactions were made by Medtronic. The redacted portion of the Reply pertains to Medtronic's claims about its projected sales if the '233 patent is not extended. It is noted that an unredacted version of the Reply has been filed with the Court, under seal. Should the USPTO desire or need to review the redacted portion of Medtronic's Reply, Applicant will approach Medtronic to seek permission to submit the unredacted version of the Reply.

Citizen's Petition Filed by AngioScore, Inc.

On August 21, 2008, AngioScore, Inc. filed a Citizen's Petition with the FDA requesting that the FDA deny the patent term extension of the '233 Patent (FDA docket no. FDA-2008-P-

0473-001/CP). A copy of the Citizen's Petition is attached as Appendix G. This Petition is currently under review by Abbott.

Conclusion

Applicant believes the '233 Patent is eligible for an extension pursuant to 35 U.S.C. §156 based upon FDA approval of the XIENCE™ V EECSS. Applicant respectfully submits that neither the background of the various rapid exchange products nor the allegations and positions asserted by Medtronic and AngioScore, Inc. adversely impact the eligibility of the '233 Patent for such an extension. However, Applicant submits the information and materials provided herewith for consideration by the USPTO and the FDA. The USPTO or FDA are invited to contact the undersigned with any questions or requests additional information regarding this matter.

Applicant authorizes the Commissioner to charge any fees and/or credit any overpayments associated with this submission to Baker Botts L.L.P. Deposit Account No. 02-4377, Ref. No. 077843.0113.

Date: September 22, 2008

Respectfully submitted,

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APPENDIX LIST

Appendix A Interview Summary filed September 12, 2008, in U.S. Patent No. 5,451,233 (U.S.S.N. 08/208,972)

Appendix B Rapid Exchange Product and Approval Summary

Appendix C Summary of Actions involving U.S. Patent No. 5,451,233

Appendix D Medtronic, Inc.'s Notice of Motion and Motion to Modify Injunction after October 29, 2008; Memorandum of Points and Authorities In Support Thereof, dated August 14, 2008 (with accompanying Exhibits)

Appendix E Plaintiff's Opposition To Defendant's Motion To Modify The Permanent Injunction (Redacted Version for Public Viewing), dated September 12, 2008 (with accompanying Exhibits)

Appendix F Medtronic, Inc.'s Reply Memorandum of Points And Authorities in Support of its Motion to Modify Injunction after October 29, 2008, (Public Version) dated September 19, 2008 (with accompanying Exhibits)

Appendix G Citizen Petition filed on behalf of AngioScore, Inc. with to the with the Federal Drug Administration, dated August 19, 2008 (with accompanying Appendices)